Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 2026

The effect of boron citrate supplementation on nutritional status, cardiometabolic factors, and inflammatory indices of TNF-α, IL-10, IL-6, and CRP and serum level of thyroid hormones and oxidative stress indices of SOD, PAB, GPx, TAC and gene expression of TNF-α, IL-10, IL-6, CRP, PPAR-γ، SIRT1، PGC-1α و AMPK in obese people

Protocol summary

Study aim
The effect of boron citrate supplementation on nutritional status, cardiometabolic factors, inflammatory indices, serum level of thyroid hormones and oxidative stress indices in obese people

Design
randomized, double-blinded, controlled trial, containing supplement and intervention groups, with parallel groups, sample size of 60 participants (30 in each group), RAS (Random Allocation Software) used for randomization.

Settings and conduct
This study will be conducted on 60 obese patients at Tabriz University of Medical Sciences Faculty of Nutrition. Patients will be divided into 2 equal groups of supplement and placebo and will receive boron citrate and placebo (maltodextrin) respectively for 12 weeks. In order to blind all researchers and participants, a person not involved in the experiment randomly assigns a list to the participants in each group and labels all identical containers (in appearance and color) according to their number. Therefore, participants will be unaware of the type of intervention they are receiving. The random sequence will also be unpredictable.

Participants/Inclusion and exclusion criteria
Inclusion criteria: obese people/Exclusion criteria: pregnancy and breastfeeding, smoking, following special diets 3 months before the study, taking chemical or herbal weight loss drugs, taking hepatotoxic drugs, taking blood pressure control drugs and blood lipid-lowering drugs

Intervention groups
Participants will be divided into two groups of 30 people: intervention group (1 capsule containing 10 mg boron citrate per day before lunch) and placebo group (1 capsule per day of maltodextrin before lunch) and will use the supplement or placebo for 12 weeks.

Main outcome variables
glucose-insulin-HbA1c-insulin resistance with HOMA-IR score, lipid pattern, systolic and diastolic blood pressure) CRP, TNF-α, IL-10, and IL-6

General information

Reason for update
Delay in obtaining the necessary financial credit to start the project

Acronym

IRCT registration information
IRCT registration number: **IRCT20220806055624N1**
Registration date: **2022-08-31, 1401/06/09**
Registration timing: **prospective**

Last update: **2024-08-29, 1403/06/08**
Update count: **3**

Registration date
2022-08-31, 1401/06/09

Registrant information

Name
Helda Tutunchi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3335 7580

Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-06-20, 1402/03/30

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of boron citrate supplementation on nutritional status, cardiometabolic factors, and inflammatory indices of TNF-α, IL-10, IL-6, and CRP and serum level of thyroid hormones and oxidative stress indices of SOD, PAB, GPx, TAC and gene expression of TNF-α, IL-10, IL-6, CRP, PPAR-γ، SIRT1، PGC-1α و AMPK in obese people

Public title
Boron citrate in obesity

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
BMI: 30–40 (kg/m²) Willingness to participate in the study

Exclusion criteria:
Athlete, pregnancy, lactation and menopause in women Under infertility treatment, taking birth control pills and estrogen Smoking and history of alcohol consumption Following a special diet three months before the study Use of chemical or herbal drugs for weight loss and use of hepatotoxic drugs such as phenytoin, amoxifene, lithium, blood pressure control drugs and blood lipid lowering drugs (statins), drugs that increase insulin sensitivity. Taking antibiotics or supplements affecting liver enzyme levels Weight loss surgery in the last year or strict weight loss diets in the last three months Using corticosteroid and non-steroidal anti-inflammatory drugs and any supplements for 3 months before the study or during the study Cardiovascular diseases, liver, kidney, intestinal, thyroid and parathyroid dysfunction, biliary disease, known autoimmune diseases, polycystic ovary syndrome, cancers and malabsorption diseases such as sprue and Crohn's Having symptoms of infectious or inflammatory disease or recent surgery Performed or candidate for liver transplant

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To stratify individuals into distinct strata and blocks, stratified block randomization will be implemented based on age (18-40 vs. 40-60 years) and gender (male vs. female). For each individual placed in a given stratum, a matched individual is considered based on these variables in the same stratum. As a result, two participants with similar characteristics (for age and gender) are placed in the same stratum. Finally, each stratum will be randomly allocated to the intervention or control groups using Random Allocation Software (RAS). Participants and researchers will be blinded to the randomization and allocation until the end of the study. The randomization list will be provided by the pharmacist of the research center at the end of the study.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, patients and researchers will be blind to the type of supplements (boron citrate or placebo). The person responsible for preparing the supplement packages (a person completely unrelated to the study) will be asked to assign a three-digit code to each of the two received supplements (boron citrate or placebo) and keep the codes for himself until the end of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The specialized committee of ethics in biomedical research

Street address
Daneshgah street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Approval date
2022-07-11, 1401/04/20

Ethics committee reference number
IR.TBZMED.REC.1401.350

Health conditions studied

1

Description of health condition studied
obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Weight
Timepoint
Beginning and end of the trial
Method of measurement
Weight scale

2

Description
Body mass index (BMI)
Timepoint
Beginning and end of the trial
Method of measurement
Calculation based on formula

3

Description
Waist circumference (WC)
Timepoint
Beginning and end of the trial
Method of measurement
Tape measure

4

Description
Waist to hip ratio (WHR)
Timepoint
Beginning and end of the trial
Method of measurement
Calculation based on formula

5

Description
Waist to height ratio (WHtR)
Timepoint
Beginning and end of the trial
Method of measurement
Calculation based on formula

6

Description
C-reactive protein (CRP)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

7

Description
Tumor necrosis factor-α (TNF-α)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

8

Description
Interleukin-10 (IL-10)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

9

Description
Interleukin-6 (IL-6)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

10

Description
Hip circumference (HC)
Timepoint
Beginning and end of the trial
Method of measurement
Tape measure

Secondary outcomes

1

Description
Fasting blood sugar (FBS)
Timepoint
Beginning and end of the trial
Method of measurement
Use of an enzymatic kit method

2

Description
Fasting insulin levels
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

3

Description

Insulin resistance with HOMA-IR score
Timepoint
Beginning and end of the trial
Method of measurement
Calculation based on formula

4

Description
Low density lipoprotein cholesterol (LDL-c)
Timepoint
Beginning and end of the trial
Method of measurement
Calculation based on the Friedewald formula

5

Description
High density lipoprotein cholesterol (HDL-c)
Timepoint
Beginning and end of the trial
Method of measurement
Use of an enzymatic kit method

6

Description
Total cholesterol (TC)
Timepoint
Beginning and end of the trial
Method of measurement
Use of an enzymatic kit method

7

Description
Triglyceride (TG)
Timepoint
Beginning and end of the trial
Method of measurement
Use of an enzymatic kit method

8

Description
Systolic blood pressure (SBP)
Timepoint
Beginning and end of the trial
Method of measurement
Mercury manometer

9

Description
Diastolic blood pressure (DBP)
Timepoint
Beginning and end of the trial
Method of measurement
Mercury manometer

10

Description
Quantitative insulin sensitivity check index (QUICKI)
Timepoint
Beginning and end of the trial
Method of measurement
Calculation based on formula

11

Description
Serum level of triiodothyronine (T3)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

12

Description
Serum level of tetraiodothyronine (T4)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

13

Description
Serum level of thyroid Stimulating hormone (TSH)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

14

Description
Prooxidant - Antioxidant balance (PAB)
Timepoint
Beginning and end of the trial
Method of measurement
ELISA

15

Description
Superoxide dismutase (SOD)
Timepoint
Beginning and end of the trial
Method of measurement
Spectrophotometric method and the Randox kit

16

Description
Glutathione Peroxidase (GPX)
Timepoint
Beginning and end of the trial
Method of measurement
Spectrophotometricmethod and the Randox kit

17

Description
Total antioxidant capacity (TAC)
Timepoint

Beginning and end of the trial

Method of measurement

Spectrophotometricmethod and the Randox kit

18

Description

Gene expression of CRP

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

19

Description

Gene expression of TNF-α

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

20

Description

Gene expression of IL-6

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

21

Description

Gene expression of IL-10

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

22

Description

Gene expression of AMPK

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

23

Description

Gene expression of PPAR-γ

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

24

Description

Gene expression of SIRT1

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

25

Description

Gene expression of PGC-1α

Timepoint

Beginning and end of the trial

Method of measurement

Real-Time polymerase chain reaction (PCR) method

26

Description

Total body fat mass (FM)

Timepoint

Beginning and end of the trial

Method of measurement

Bioelectrical impedance analysis

27

Description

Total body fat free mass (FFM)

Timepoint

Beginning and end of the trial

Method of measurement

Bioelectrical impedance analysis

Intervention groups

1

Description

Intervention group: Patients in this group will receive dietary recommendations and boron citrate capsules including 10 mg boron for 12 weeks. Boron citrate capsules is made in Iran, and once a day before lunch will be consumed.

Category

Prevention

2

Description

Control group: Patients in this group will receive dietary recommendations with placebo for 12 weeks. The placebo is starch (containing 10 mg of maltodextrin) and once a day before lunch will be consumed.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Research Center of Tabriz University of Medical Sciences

Full name of responsible person

Helda Tutunchi
Street address
Nutrition faculty, Tabriz University of Medical Science, Golgasht Avenue, Attar Neyshabouri Street
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5166614711
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Parviz Shahabi
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Tabriz University of Medical Sciences, Attar Neishabouri Street, Golgasht Avenue
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5166614711
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+98 41 3335 7580
Email
parvizshahabi@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Helda Tutunchi
Position
Assistant Professor of Nutritional Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared.
When the data will become available and for how long
access starting 12 months after publication
To whom data/document is available
The data will only be available for people working in academic institutions.
Under which criteria data/document could be used
The data of the present study will only be accessible by other researchers, for conducting Meta-analysis.
From where data/document is obtainable
The researchers (student and her supervisor)
What processes are involved for a request to access data/document
Request a document via email
Comments